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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,782	08/13/2001	Robert O. Ralston	154.206	1144

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EXAMINER	
HILL, MYRON G	
ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/929,782	Applicant(s) RALSTON ET AL.	
	Examin r Myron G. Hill	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *20- 23,and 57- 79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20- 23,and 57- 79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6 February 2003 has been entered.

Claims 20- 23 and 56- 79 are under consideration in this action.

Response To Arguments After RCE

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20- 23 and 56- 79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term “specific” in the phrase "antibody specific for said hepatitis c virus (HCV) glycoprotein" is a relative term which

renders the claim indefinite. Applicant has amended the "specific" to be "directed against".

Applicant's argued that it is clear that the antibody is specific for "said" HCV antigen, that this term is understood in the art, and that it does not denote "absolute" specificity.

Applicant's argument has been fully considered and not found persuasive.

The metes and bounds of either term, "specific" or "directed against", used to describe the antibody is not clear and is not defined in the specification in such a way to know what specificity is envisioned. It is not clear that the antibody is directed against the asialoglyco part, the amino acid residues or conformation of native protein. It is not clear how this antibody differs from one that binds to sialated glycoprotein. Thus, not knowing the basis of specificity, the claim is not clear.

The rejection is maintained.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20- 23, and 56- 79 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antigen production, does not reasonably provide enablement for specific antibodies and were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for concept

of using an antigen to make an antibody, does not reasonably provide enablement for making an antibody for the stated antigen.

Applicant argues the claims have been amended to recite "directed against" and this overcomes the basis of the rejection.

Applicant's argument has been fully considered and not found persuasive.

As discussed above in the 112 second rejection, it is not clear what specificity is required of the antibody and how this is different from other antibodies. Without knowing this, it is not possible to know when the antibody of the invention is made.

The rejection is maintained.

Claims 20- 23, and 44- 79 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant argues the specification meets the requirement for written description and that Applicant contemplates antibodies as shown on page 5, lines 2- 4.

Applicant's argument has been fully considered and not found persuasive.

The specification does not contemplate all the antibodies recited in the claims as they now stand. The Disclosure of the Invention (pages 3 and 4) does not mention antibodies. The level of skill in the art of antibodies was high at the time of filing; however, the specification contains no reference to physical properties or structure of the antibody nor does it teach antibodies "directed against" E1 or E2. As Applicant

states, they **contemplated** antibodies (emphasis added). Applicant cites from *Vas-Cath Inc. v. Mahurkar* ((CAFC, 1991) 19 USPQ2d 1111), which states that "Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See *Vas-Cath* at page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). Applicant may have contemplated the antibodies but did not convey in the specification that they were in fact in possession of the claimed antibodies.

To comply with the written description requirement of 35 U.S.C. § 112, first paragraph, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas. These may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the use of drawings or structural chemical formulas that show that the invention was complete, or describing distinguishing identifying characteristics sufficient to show that the applicant was in Possession of the claimed invention. Applicant has not provided any details that allow one of skill in the art to know that the antibody of the invention has been made or that

the contemplation defines an antibody that is different than disclosed by Houghton as discussed below.

The rejection of record is maintained.

New Rejections

Claim Rejections - 35 USC § 102/ 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 20- 23, and 56- 79 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Houghton (EP 318 216).

Houghton discloses an isolated antibody that is reactive with asialoglycoproteins of HCV E1 and/or E2 (at least at page 56, lines 33- 44).

The isolated antibodies disclosed by Houghton do not state the limitation of asialoglycoprotein E1 and E2 of HCV but the antibodies contained in this serum would inherently contain anti- E1 and E2 antibodies and the glycosilation state is a quality of

the viral antigen which they are directed against or specific for even if it was not known at the time. Claims are directed to an antibody and thus the antibody disclosed by Houghton meets the limitations of the claims.

Houghton also discloses that antibodies bound to a solid support can be used to capture and detect HCV (page 50, top half of page and claim 30).

One of skill in the art at the time of the invention would have been able to use the isolated antibodies to make a kit to detect HCV.

Thus, the antibody of Houghton meets the limitation of the claimed antibody and it would have been prima facie obvious to make a kit to detect the presence of HCV using the antibody with the expectation of success.

Conclusion

All claims remain rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Myron G. Hill
Patent Examiner
June 28, 2003

JAMES HOUSEL 6/30/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600